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Francisco Javier Vila Pahi

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

The amendment filed 7/25/2008 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

1. Claim 18 has been canceled.
2. Claims 1-17 and 19-25 have been amended.
3. Remarks drawn to objection to specification and rejections under 35 USC 101 and 112, second paragraph

Claims 1-1-17 and 19-25 are pending in the case. The rejections below are made of record necessitated by amendments.

Specification

The objection to the Specification has been overcome by filing the Abstract on a separate sheet.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of Claims 1-25 under 35 U.S.C. 101 has been overcome by amendments to claims 1-17 and 19-25, which are now drawn to method of prophylaxis and treatment of osteoarthritis. The rejection of claim 18 has been rendered moot by cancellation of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 19-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of osteoarthritis, does not reasonably provide enablement for the prophylaxis of osteoarthritis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

- (A) The breadth of the claims
- (B) The state of the prior art
- (C) The level of predictability in the art
- (D) The amount of direction provided by the inventor
- (E) The existence of working examples
- (F) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

Claims 1-17 and 19-25 are drawn to a method of prophylaxis of osteoarthritis via administration to a mammal in need thereof an effective amount of specific sulfated polysaccharides. Applicants have not provided a definition for the term prophylaxis. The ordinary dictionary meaning (Dictionary.com) of the term prophylaxis is prevention of a

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disease. The scope of the claims is seen to include the administration of the said compounds to a healthy mammal, and subsequent exposure to conditions that would cause osteoarthritis, wherein the said compounds prevents said exposure from manifesting itself in said mammal so exposed.

The state of the prior art

The examiner notes that the art used in the rejections below and WO 03/006645 cited by the applicants teach treatment of osteoarthritis, rheumatoid arthritis and other antiinflammatory conditions. The art is silent regarding the prophylaxis of osteoarthritis using sulfated polysaccharides.

The level of predictability in the art

Based on the teaching of the prior art above there is not seen sufficient data to substantiate the prevention of osteoarthritis using a sulfated polysaccharide as instantly claimed. Based on the teaching of the prior art the prevention of osteoarthritis is highly unpredictable.

The amount of direction provided by the inventor

Even though the instant specification provides a reference to laminarin sulfate as a heparanase inhibitor and its association with arthritis it is still not seen to provide enough guidance that would allow a skilled artisan to extrapolate from the disclosure and the examples provided to enable the prevention of osteoarthritis using a single active agent as instantly claimed.

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The existence of working examples

The working examples set forth in the instant specification are drawn to the effect of inulin polysulfate on the synthesis of aggrecans. One of ordinary skill in the art will not extrapolate the results of the instant examples to the prevention of osteoarthritis using the active agent as instantly claimed.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure

Indeed, in view of the information set forth, the instant disclosure is not seen to be sufficient to enable the prevention or prophylaxis of osteoarthritis as instantly claimed. One of ordinary skill in the art would have to perform additional experimentation with different sulfated polysaccharides using healthy mammals, with regard to variables the dosage and frequency, etc. in order to determine the preventive efficacy of the instant active agents.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been overcome by amendments.

The following rejections are made of record necessitated by amendment.

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Claims 5, 9-11 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "partially" in claim 5 is a relative term which renders the claim indefinite. The term "partially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purpose of prosecution a salification in the range of 0.1 to 99.9% is interpreted as partial salification in this and all other claims in which the said term is recited.

Claims 9-10 recite the terms, 'on anhydrous base'. It is not clear what applicants intend by the said recitation.

The terms "portion of the structure" in claim 23 are relative terms which render the claim indefinite. The term "portion of the structure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. For purpose of prosecution any structural feature that corresponds to a structural feature in the sulfated polysaccharides recited in the claim is interpreted as reading on the said limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-17 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cullis-Hill et al (US 5,145,841) in combination with Dictionary.com (2002, page 3), and Komai et al (International Journal of Biological Macromolecules, 2002, 30, 197-204).

Hill et al, drawn to antiinflammatory compounds, teach that polysulfated polysaccharides like alginic acid, pectin and inulin have a variety of biological activities including antiinflammatory activity (col. 5, lines 53-64) and are useful for treatment of osteoarthritis via direct injection into the synovial cavity of an arthritic joint (col. 7, lines 39-40; col. 8, lines 46-59; col. 12, lines 8-26). The said sulfated polysaccharides can also be used as their salts (col. 9,

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lines 55-58). However, Hill et al do not exemplify the treatment of osteoarthritis using the polysulfated polysaccharides as instantly claimed.

Komai et al, drawn to rheumatoid arthritis, teach the use of gellan sulfate which acts as a ligand for extra domain A containing fibronectin, which is found to be in high concentration in patients with rheumatoid arthritis (abstract; page 198, first full paragraph and figure 2). However, Komai et al do not specifically teach or exemplify the use of gellan sulfate for the treatment of osteoarthritis.

According to the definitions in Dictionary.com both rheumatoid and osteoarthritis involve degradation of bone joints.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polysulfated polysaccharides as instantly claimed in a method of treating osteoarthritis since the use of the sulfated polysaccharides as instantly claimed is seen to be suggested for the treatment of osteo- and related rheumatoid arthritis.

One of skill in the art would be motivated to use the active agents in the method of treatment as instantly claimed since they inhibit the release and the action of the serine proteinases. The proteoglycans, which confer the property of resilience of the joints, are depleted due to excessive degradation of proteinases. Hence inhibition of the degradation of the proteinases inhibits the depletion of the proteoglycans, which are needed to maintain the resilience of joints. One of skill in the art would expect the structurally related polysulfate polysaccharides to perform the same functions and would look for other related sulfated polysulfated polysaccharides for use in the method of treatments as instantly claimed.

Conclusion

Claims 1-17 and 19-25 are rejected

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623

/Ganapathy Krishnan/
Examiner, Art Unit 1623